

SPEDRA[®] TABLET

Avanafil (50 mg, 100 mg, 200 mg)

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What Spedra is used for

Spedra contains the active substance avanafil. It belongs to a group of medicines called phosphodiesterase type 5 (PDE5) inhibitors. Spedra is a treatment for adult men suffering from erectile dysfunction (also known as impotence). This is when you cannot get, or keep a hard, erect penis suitable for sexual activity.

Spedra will not help you if you do not have erectile dysfunction. Spedra is not for women.

How Spedra works

Spedra works by helping the blood vessels in your penis to relax. This increases the blood flow into your penis, helping it stay hard and erect when you get sexually excited. Spedra does not cure your condition.

It is important to note that Spedra only works if you are sexually stimulated. You and your partner will still need to use foreplay to get ready for sex – just as you would if you were not taking a medicine to help you.

Before you use Spedra

- When you must not use it

- If you are allergic to avanafil or any of the other ingredients of this medicine.
- If you are taking “nitrate” medicines for chest pain (angina), such as amyl nitrite or glyceryl

trinitrate. Spedra can increase the effects of these medicines and severely lower your blood pressure.

- If you are taking medicines for HIV or AIDS such as ritonavir, indinavir, saquinavir, nelfinavir or atazanavir.
- If you are taking medicines for fungal infections such as ketoconazole, itraconazole or voriconazole or certain antibiotics for bacterial infections, such as clarithromycin or telithromycin.
- If you have a serious cardiac problem.
- If you have had a stroke or heart attack in the last 6 months.
- If you have low blood pressure or high blood pressure not controlled by medicines.
- If you have chest pain (angina) or you get chest pain during sexual intercourse.
- If you have a serious liver or kidney problem.
- If you have loss of vision in one eye due to not enough blood getting to your eye (non-arteritic ischemic optic neuropathy [NAION]).
- If certain serious eye problems run in your family (such as retinitis pigmentosa).
- If you are taking riociguat. This drug is used to treat pulmonary arterial hypertension (i.e., high blood pressure in the lungs) and chronic thromboembolic pulmonary hypertension (i.e., high blood pressure in the lungs secondary to blood clots). PDE5 inhibitors have been shown to increase the hypotensive effects of this medicine. If you are taking riociguat or are unsure tell your doctor.

Do not take Spedra if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist before taking Spedra.

- Before you start to use it

Talk to your doctor or pharmacist before taking Spedra:

- If you have heart problem. It may be risky for you to have sexual intercourse.
- If you suffer from priapism, that is a persistent erection lasting 4 hours or more. This can happen in men with conditions like sickle cell disease, multiple myeloma or leukaemia.
- If you have a physical condition that affects the shape of your penis (such as angulation, Peyronie’s disease or cavernosal fibrosis).
- If you have any bleeding disorder or active peptic ulceration.

If any of the above apply to you talk to your doctor or pharmacist before taking Spedra. Check with your doctor or pharmacist if you are not sure.

- Taking other medicines

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This is because Spedra can affect the way some other medicines work. Also some other medicines can affect the way Spedra works.

In particular, tell your doctor and do not take Spedra if you are taking “nitrate” medicines for chest pain (angina) such as amyl nitrite or glyceryl trinitrate. Spedra has been shown to increase the effects of these medicines and severely lower your blood pressure. Also do not take Spedra if you are taking medicines for HIV or AIDS such as ritonavir, indinavir, saquinavir, nelfinavir or atazanavir or if you are taking medicines for fungal infections such

as ketoconazole, itraconazole or voriconazole or certain antibiotics for bacterial infections, such as clarithromycin or telithromycin. Tell

your doctor or pharmacist if you are taking any of the following medicines:

- so called “alpha-blockers” – for prostate problems or for lowering your high blood pressure.
- medicines for an irregular heartbeat (“arrhythmia”) such as quinidine, procainamide, amiodarone or sotalol.
- antibiotics for infections such as erythromycin.
- phenobarbital or primidone – for epilepsy.
- carbamazepine – for epilepsy, to stabilise your mood or for certain types of pain.
- other medicines that may reduce the breakdown of Spedra in the body (‘moderate CYP3A4 inhibitors’) including amprenavir, aprepitant, diltiazem, fluconazole, fosamprenavir, and verapamil
- riociguat.
- Do not use Spedra together with other treatments for erectile dysfunction such as sildenafil, tadalafil or vardenafil.

If any of the above apply to you talk to your doctor or pharmacist before taking Spedra. Check with your doctor or pharmacist if you are not sure.

How to use Spedra

- How much to use

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is a 100 mg tablet, as needed. You should not take Spedra more than once a day. You could have been given the dose of one 200 mg tablet if your doctor has decided that the 100 mg dose was too weak for you, or the dose of one 50 mg tablet if your doctor has decided that the 100 mg tablet was too strong for you.

Dose adjustments can also be required if Spedra is used together with certain other medicines. If you are taking a medicine such as erythromycin, amprenavir, aprepitant, diltiazem,

fluconazole, fosamprenavir or verapamil (‘moderate CYP3A4 inhibitors’) the recommended dose of Spedra is a 100 mg tablet, with an interval of at least 2 days between doses.

- When to use it

You should take Spedra about 30 minutes before you have sexual intercourse. Remember that Spedra will only help you to get an erection if you are sexually stimulated.

Spedra can be taken with or without food; if taken with food, it may take longer to work.

- How long to use it

Continue taking Spedra for as long as your doctor recommends.

- If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

- If you use too much (overdose)

If you take too much Spedra, you should tell your doctor straight away. You may get more side effects than usual and they may be worse.

If you have any further questions on the use of Spedra, ask your doctor or pharmacist.

While you are using it

- Things you must do

Take your medicine exactly as your doctor has told you.

- Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

Do not give Spedra to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Children and adolescents

Spedra should not be taken by children and adolescents under 18 years of age.

Spedra with drink and alcohol

Grapefruit juice can increase exposure to the medicine and should be avoided within 24 hours prior to taking Spedra. Drinking alcohol at the same time as taking Spedra may increase your heart rate and lower your blood pressure. You may feel dizzy (especially when standing), have a headache or feel your heart beating in your chest (palpitations). Drinking alcohol may also decrease your ability to get an erection.

Fertility

There was no effect on sperm movement or structure after single 200 mg oral doses of avanafil in healthy volunteers.

The repeated oral administration of avanafil 100 mg over a period of 26 weeks to healthy volunteers and adult males with mild erectile dysfunction was not associated with any untoward effects on sperm concentration, count, motility, or morphology.

Driving and using machines

Spedra can make you feel dizzy or affect your vision. If this happens, do not drive, cycle, use tools or machines.

Side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Problems with your sight or hearing

Some men taking medicines like Spedra have had problems with their sight and hearing.

It is not known if these problems are related directly to Spedra, other diseases that you may have or a combination of factors.

If you experience sudden decrease or loss of vision or your vision is distorted or dimmed while you are taking Spedra, stop taking Spedra and contact your doctor immediately.

Serious side effects

Stop taking Spedra and see a doctor straight away if you notice any of the

following serious side effects – you may need urgent medical treatment:

- an erection that will not go away (“priapism”). If you get an erection that lasts more than 4 hours, this must be treated as soon as possible or lasting damage can happen to your penis (including not being able to get erections).
- blurred vision.
- sudden decrease or loss of vision in one or both eyes.
- sudden decrease or loss of hearing (sometimes you may also feel dizzy or have ringing in your ears).

Stop taking Spedra and see a doctor straight away, if you notice any of the serious side effects above.

Other side effects

Common (may affect up to 1 in 10 people)

- headache.
- flushing.
- nasal congestion.

Uncommon (may affect up to 1 in 100 people)

- feeling dizzy.
- feeling sleepy or very tired.
- sinus congestion.
- back pain.
- hot flush.
- feeling out of breath when you exert yourself.
- heartbeat changes seen on a heart tracing (ECG).
- increased heart beat.
- feeling your heartbeat in your chest (palpitations).
- indigestion, feeling or being sick to your stomach.
- blurry vision.
- raised liver enzymes.

Rare (may affect up to 1 in 1,000 people)

- influenza.
- influenza-like illness.
- stuffy or runny nose.
- hay fever.

- congestion in the nose, sinuses or upper part of the airway bringing air into the lungs.
- gout.
- trouble sleeping (insomnia).
- premature ejaculation.
- feeling strange.
- feeling unable to keep still.
- chest pain.
- serious chest pain.
- fast heart beat.
- high blood pressure
- low blood pressure
- dry mouth.
- stomach ache or heartburn.
- pain or discomfort in the lower abdomen.
- diarrhea.
- rash.
- pain in the lower back or side of lower chest.
- muscle aches or pains.
- muscle spasms.
- frequent urination.
- penile disorder.
- spontaneous erection without sexual stimulation.
- itching in the genital area.
- feeling weak or tired all the time.
- swelling in the feet or ankles.
- increased blood pressure.
- pink or red urine, blood in the urine.
- abnormal extra sound from the heart.
- an abnormal blood test result for a prostate test called ‘PSA’.
- an abnormal blood test result for bilirubin, a chemical produced from the normal breakdown of red blood cells.
- an abnormal blood test result for creatinine, a chemical excreted in the urine, and a measure of kidney function.
- weight gain.
- fever.
- nosebleed.

Visit your doctor or pharmacist immediately if you experience any side effects after using this medicine.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of Spedra

- Storage

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the blister and carton after “EXP”.

The expiry date refers to the last day of that month.

This medicine does not require any special storage condition.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Ask your pharmacist how to throw away medicines you no longer use.

Product Description

- What it looks like

- The tablets are provided in blister packs containing 2, 4, 8, or 12 tablets.
- 50 mg: Spedra is a pale yellow oval tablet, marked “50” on one side.
- 100 mg: Spedra is a pale yellow oval tablet, marked “100” on one side.
- 200 mg: Spedra is a pale yellow oval tablet, marked “200” on one side.

- Ingredients

- Active ingredient(s)

Avanafil.

- Inactive ingredients

Mannitol, fumaric acid, hydroxypropylcellulose, low substituted hydroxypropylcellulose, calcium carbonate, magnesium stearate and ferric oxide yellow (E172).

- MAL number:
Spedra 50mg Tablets :
MAL22016001AZ

Spedra 100mg Tablets :
MAL22016002AZ

Spedra 200mg Tablets :
MAL22016003AZ

Manufacturer

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Product Registration Holder:

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